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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Makoto ASASHIMA et al.

Confirmation No. 1458

Group Art Unit: unknown

Serial No. : 10/549,816 (National Phase of PCT/JP2004/003578)

Examiner: unknown

I.A. Filed : March 17, 2004

For : METHOD OF FORMING ORGAN

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Pursuant to 37 C.F.R. § 1.56 and 37 C.F.R. §§ 1.97-1.98, Applicants hereby direct the Examiner's attention to the following documents cited in the International Search Report for International Application PCT/JP2004/003578, of which the above-referenced application is a national stage:

- (1) SEWTER C.P. et al., "Regional Differences in the Response of Human Pre-Adipocytes to PPAR γ and RXR α Agonists", Diabetes (2002), vol. 51, No. 3, pp. 718-723;
- (2) KIM M.J. et al., "Limited Cooperation between Peroxisome Proliferator-Activated Receptors and Retinoid X Receptors Agonists in Sebocyte Growth and Development", Molecular Genetics and Metabolism (2001), vol. 74, No.3, pp. 362-369;
- (3) MILLION K. et al., "Effects of Retinoic Acid Receptor-Selective Agonists on Human Nasal Epithelial Cell Differentiation" American

- Journal of Respiratory Cell and Molecular Biology (2001), vol. 25, No.6, pp. 744-750;
- (4) SHIBAKURA M. et al., "A Retinoic Acid Receptor- α (RAR α) Selective Agonist Modulates Procoagulant Activity of Acute Promyelocytic Cells and Induces Their Differentiation Into Neutrophils", Blood (1998), vol. 91, No. 2, pp. 724-725;
 - (5) WESTON A.D. et al., "Regulation of Skeletal Progenitor Differentiation by the BMP and Retinoid Signaling Pathways", The Journal of Cell Biology (2000), vol. 148, No. 4, pp. 679-690;
 - (6) EP 1 285 961 A1, February 26, 2003;
 - (7) U.S. Patent Application Publication No. 2003/0109035 A1 (ASASHIMA et al.), June 12, 2003; Applicants note that this document is a family member of document (6);
 - (8) NAGY L. et al., "Activation of Retinoid X Receptors Induces Apoptosis in HL-60 Cell Lines", Molecular and Cellular Biology (1995), vol. 15, No. 7, pp. 3540-3551;
 - (9) EP 1 048 659 A1, November 2, 2000.

Applicants further direct the Examiner's attention to the following documents cited in the Supplementary European Search Report of European counterpart application EP 04 72 1319:

- (10) ISHIDA S. et al., "Clinically Potential Subclasses of Retinoid Synergists Revealed by Gene Expression Profiling", Molecular Cancer Therapeutics (2003), vol. 2, no. 1, pp. 49-58;

- (11) TAKAHASHI B. et al., "Novel Retinoid X Receptor Antagonists: Specific Inhibition of Retinoid Synergism in RXR-RAR Heterodimer Actions", *Journal of Medicinal Chemistry* (2002), vol. 45, no. 16, pp. 3327-3330;
- (12) HONDA M. et al., "RXR agonist enhances the differentiation of cardiomyocytes derived from embryonic stem cells in serum-free conditions", *Biochemical and Biophysical Research Communications* (2005), vol. 333, no. 4, pp. 1334-1340;
- (13) COLLINS S.J., "The HL-60 Promyelocytic Leukemia Cell Line: Proliferation, Differentiation, and Cellular Oncogene Expression", *Blood* (1987), vol. 70, no. 5, pp. 1233-1244;
- (14) MONTESANO R. et al., "Retinoids induce lumen morphogenesis in mammary epithelial cells", *Journal of Cell Science* (2002), vol. 115, no. 23, pp. 4419-4431;
- (15) RAZ Y. et al. "Retinoic Acid Signaling is Necessary for the Development of the Organ of Corti", *Developmental Biology* (1999), vol. 213, no. 1, pp. 180-193;
- (16) TRAN C.M. et al., "The RXR α gene functions in a non-cell-autonomous manner during mouse cardiac morphogenesis", *Development* (1998), vol. 125, no. 10, pp. 1951-1956.

Furthermore, Applicants direct the Examiner's attention to the following copending applications:

- (17) U.S. Patent Application Publication No. 2003/0191342 A1 (KAGECHIKA et al.), October 9, 2003;
- (18) U.S. Patent Application Publication No. 2005/0234130 A1 (NAGAI et al.), October 20, 2005;
- (19) U.S. Application No. 11/366,454 to NAGAI et al., filed March 3, 2006 and entitled "MEDICAMENT HAVING PROMOTING ACTION ON NEOVASCULARIZATION".

Copies of the above-listed documents (with the exception of the U.S. patent applications), the International Search Report for International Application PCT/JP2004/003578 (in English and Japanese), the International Preliminary Report on Patentability (in English), and the Supplementary European Search Report of European Application EP 04 72 1319 are enclosed together with a completed copy of the PTO-1449 Form listing these documents. Accordingly, the Examiner is requested to consider these documents and to indicate such consideration by returning a signed and initialed copy of the PTO-1449 Form with the next official communication.

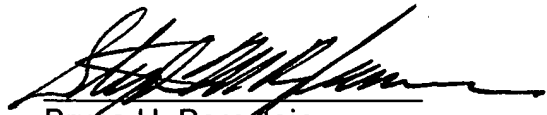
Further to 37 C.F.R. §1.98 (a)(2)(ii) and to the U.S. Patent and Trademark Office's decision to waive the requirement under 37 C.F.R. §1.98 (a)(2)(iii) for U.S. patent application filed after June 30, 2003, copies of the U.S. patent

applications are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Applicants note that an Office Action on the merits has not yet issued in the instant application, and thus, no fee is necessary to ensure consideration of this statement. However, if an Office Action has issued and is crossing in the mail with this statement, the Patent and Trademark Office is hereby authorized to charge Deposit Account No. 19-0089 any fee necessary to ensure consideration of the submitted materials.

If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,
Makoto ASASHIMA et al.



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FORM PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
P28509Application No.
10/549,816INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(Use several sheets if necessary)

Applicant
Makoto ASASHIMA et al.Filing Date
I.A. Filed March 17, 2004Group
Not Yet Known

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
02 2006	0 1 0 9 0 3 5	06/12/03	ASASHIMA et al.			
03 /	0 1 9 1 3 4 2	10/09/03	KAGECHIKA et al.			
2005 /	0 2 3 4 1 3 0	10/20/05	NAGAI et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
1 2 8 5 9 6 1	02/26/03	E.P.O.				
1 0 4 8 6 5 9	11/02/00	E.P.O.				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	SEWTER C.P. et al., "Regional Differences in the Response of Human Pre-Adipocytes to PPAR γ and RXR α Agonists", Diabetes (2002), vol. 51, No. 3, pp. 718-723.
2	KIM M.J. et al., "Limited Cooperation between Peroxisome Proliferator-Activated Receptors and Retinoid X Receptors Agonists in Sebocyte Growth and Development", Molecular Genetics and Metabolism (2001), vol. 74, No.3, pp. 362-369.
3	MILLION K. et al., "Effects of Retinoic Acid Receptor-Selective Agonists on Human Nasal Epithelial Cell Differentiation" American Journal of Respiratory Cell and Molecular Biology (2001), vol. 25, No.6, pp. 744-750.
4	SHIBAKURA M. et al., "A Retinoic Acid Receptor- α (RAR α) Selective Agonist Modulates Procoagulant Activity of Acute Promyelocytic Cells and Induces Their Differentiation Into Neutrophils", Blood (1998), vol. 91, No. 2, pp. 724-725.
5	WESTON A.D. et al., "Regulation of Skeletal Progenitor Differentiation by the BMP and Retinoid Signaling Pathways", The Journal of Cell Biology (2000), vol. 148, No. 4, pp. 679-690.
6	NAGY L. et al., "Activation of Retinoid X Receptors Induces Apoptosis in HL-60 Cell Lines", Molecular and Cellular Biology (1995), vol. 15, No. 7, pp. 3540-3551.
7	ISHIDA S. et al., "Clinically Potential Subclasses of Retinoid Synergists Revealed by Gene Expression Profiling", Molecular Cancer Therapeutics (2003), vol. 2, no. 1, pp. 49-58.
8	TAKAHASHI B. et al., "Novel Retinoid X Receptor Antagonists: Specific Inhibition of Retinoid Synergism in RXR-RAR Heterodimer Actions", Journal of Medicinal Chemistry (2002), vol. 45, no. 16, pp. 3327-3330.
9	HONDA M. et al., "RXR agonist enhances the differentiation of cardiomyocytes derived from embryonic stem cells in serum-free conditions", Biochemical and Biophysical Research Communications (2005), vol. 333, no. 4, pp. 1334-1340.
10	COLLINS S.J., "The HL-60 Promyelocytic Leukemia Cell Line: Proliferation, Differentiation, and Cellular Oncogene Expression", Blood (1987), vol. 70, no. 5, pp. 1233-1244.
11	MONTESANO R. et al., "Retinoids induce lumen morphogenesis in mammary epithelial cells", Journal of Cell Science (2002), vol. 115, no. 23, pp. 4419-4431.
12	RAZ Y. et al. "Retinoic Acid Signaling is Necessary for the Development of the Organ of Corti", Developmental Biology (1999), vol. 213, no. 1, pp. 180-193.
13	TRAN C.M. et al., "The RXR α gene functions in a non-cell-autonomous manner during mouse cardiac morphogenesis", Development (1998), vol. 125, no. 10, pp. 1951-1956.
14	U.S. Application No. 11/366,454 to NAGAI et al., filed March 3, 2006 and entitled "MEDICAMENT HAVING PROMOTING ACTION ON NEOVASCULARIZATION".

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.